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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,860	08/03/2001	Daniel E. Alesi	0100/0129	6633

21395 7590 11/13/2002

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M

**Office Action Summary**

Application No.

09/920,860

Applicant(s)

ALESI ET AL.

Examiner

Kathryn L. Thompson

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4, 13 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 14-20 and 22-26 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "2" has been used to designate both holder and housing. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "18" has been used to designate both space and double ended needle. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "18", "34", "24", and "36" have all been used to designate space. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "20" has been used to designate both needle and cannula. A proposed drawing correction or corrected drawings are required in reply to the Office

action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "2" and "12" have both been used to designate housing. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 6 is objected to because of the following informalities: In Line 2, Examiner believes that Applicant's intention was to claim "locking portion that coacts with at least" 'another' and not "an other" "locking portion..." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 10-12, 14, 15, 17-20, 22, 23, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollister (US 5,277,311). Hollister discloses an apparatus comprising a holder (2) having an extension (16) and a sleeve integrally extending from said extension, a double ended needle (28), a collar (18) rotatable about

said extension, a housing (20) comprising an integral locking means, a sheath, and a cover (Figure 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister in view of Imbert (US 6,027,482). Hollister teaches all of the claimed limitations except a tamper evident seal on said sheath and sleeve. Imbert discloses a tamper evident seal on said sheath and sleeve (Figure 8, #86). Imbert teaches that the tamper evident seal provides evidence as to whether or not the medical device has been tampered or misused (Column 6, Lines 51-58). It would have been obvious to one with ordinary skill in the art to use the teachings of Imbert to modify the invention of Hollister in order to create a safe tamper-free medical device.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Imbert (US 5,624,402), Kalin (US 5,647,849), and Garver, Sr. et al (US 4,402,682) teach a tamper evident seal. Hollister (US 5,139,489), Thorne et al

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(US 6,224,576), and Hollister (US 5,154,285) disclose a needle device with tortuous path.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLT

October 31, 2002

**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**